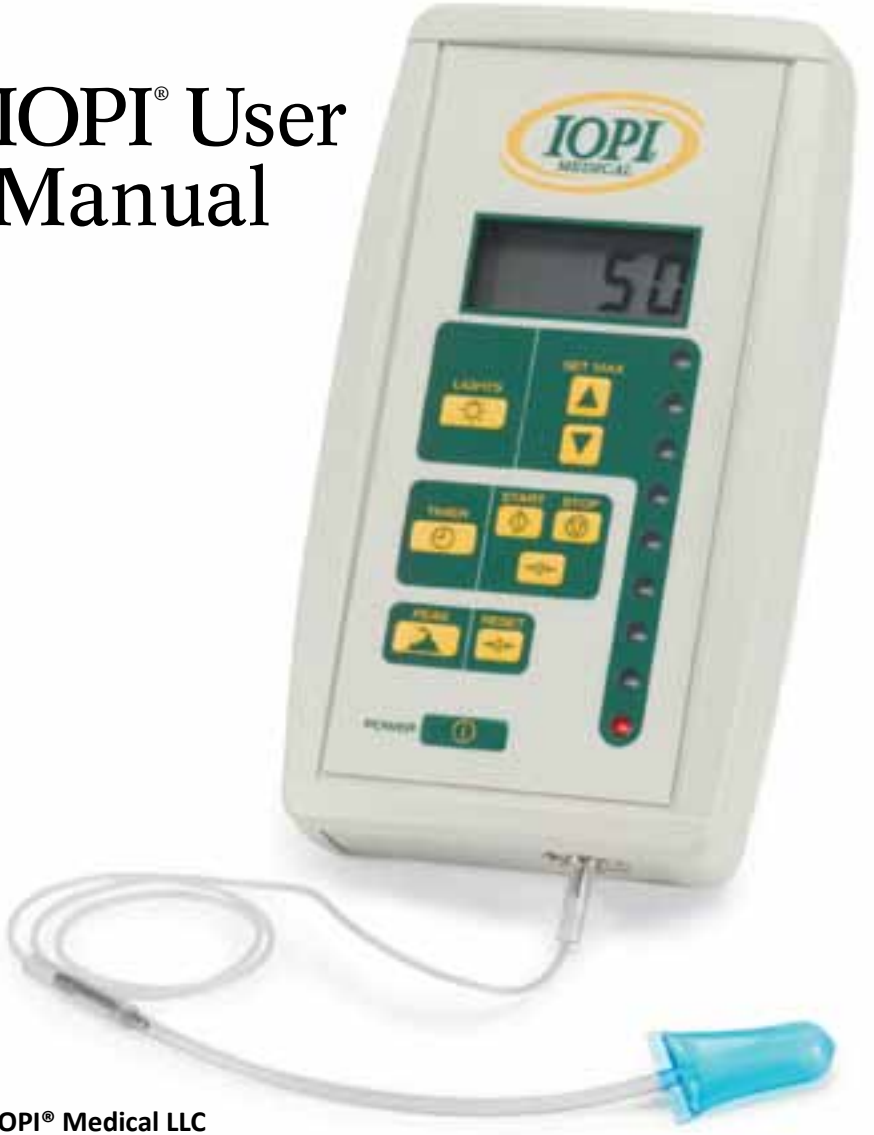
IOPI MEDICAL

Iowa Oral Performance Instrument

MODEL 2.3

IOPI® User Manual



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www.IOPImedical.com

IOPI® Icons

Symbol	Identity
	Catalogue Number
	Serial Number
	Manufacturing Date
	Consult Instructions Before Use
	Caution
	Type B patient applied part according to IEC 60601-1
4mA 9V alkaline	9 Volt Alkaline Battery
	Do Not Dispose of in Household Refuse
	EU Authorized Representative
	Manufactured By
	Conformity European

Notes:

IOPI Medical LLC is certified to ISO 13485:2003 under the Canadian Medical Device Regulation

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Indications for Use

Tongue and lip strength and endurance measurement in patients with oral motor problems, including dysphagia and dysarthria.

Contraindications:

- **Do not** use with children under the age of 3.
- **Do not** put the Tongue Bulb in a patient's mouth if there is a risk of the patient having a seizure.
- **Do not** use the Tongue Bulb with a patient who has any current or past problem with pain disorders involving the jaw muscles or joint of the mandible ("TMJ Disorder," "Myofacial Pain Disorder").

⚠ WARNINGS

- The medical professional should ensure the patient is healthy enough to perform a maximal motor task, recognizing that it may produce a generalized effort response.
- The medical professional should **hold on to the Tongue Bulb tube** any time it is in a patient's mouth.
- The Tongue Bulbs, as supplied by IOPI Medical LLC, are **not sterile and are not intended for sterilization**.
- The Tongue Bulbs, as supplied by IOPI Medical LLC, are intended for **single patient use only**. Please read the IOPI Tongue Bulb Directions for Use for cleaning instructions between uses with the same patient.
- Keep Tongue Bulbs out of the reach of children.
- The medical professional should inform any patient who is to perform the tongue endurance measurement at 50% or more of the Peak pressure that they may experience the sensation of "throat" soreness following the measurement. This condition may persist for as long as 24 hours.

IOPI® Components

Included in The IOPI System (PN 1-2300):

Component	Item	PN	Description
A	Iowa Oral Performance Instrument (IOPI) Model 2.3	**8-2301**	Device measures and displays pressure from an air-filled bulb. Pressure In port is a short stainless steel tube to which the Connecting Tube is attached (C).
B	Box of Tongue Bulbs	**5-6010**	Squeezed by the tongue to measure tongue strength and endurance.
C	Connecting Tube	**5-0001**	Connects the Tongue Bulb to the Pressure In port.
D	Carrying Case	**5-0002**	Padded case for storing and transporting the IOPI device.
E	Accuracy Check Syringe	**5-0101**	Syringe used in the Accuracy Check procedure.

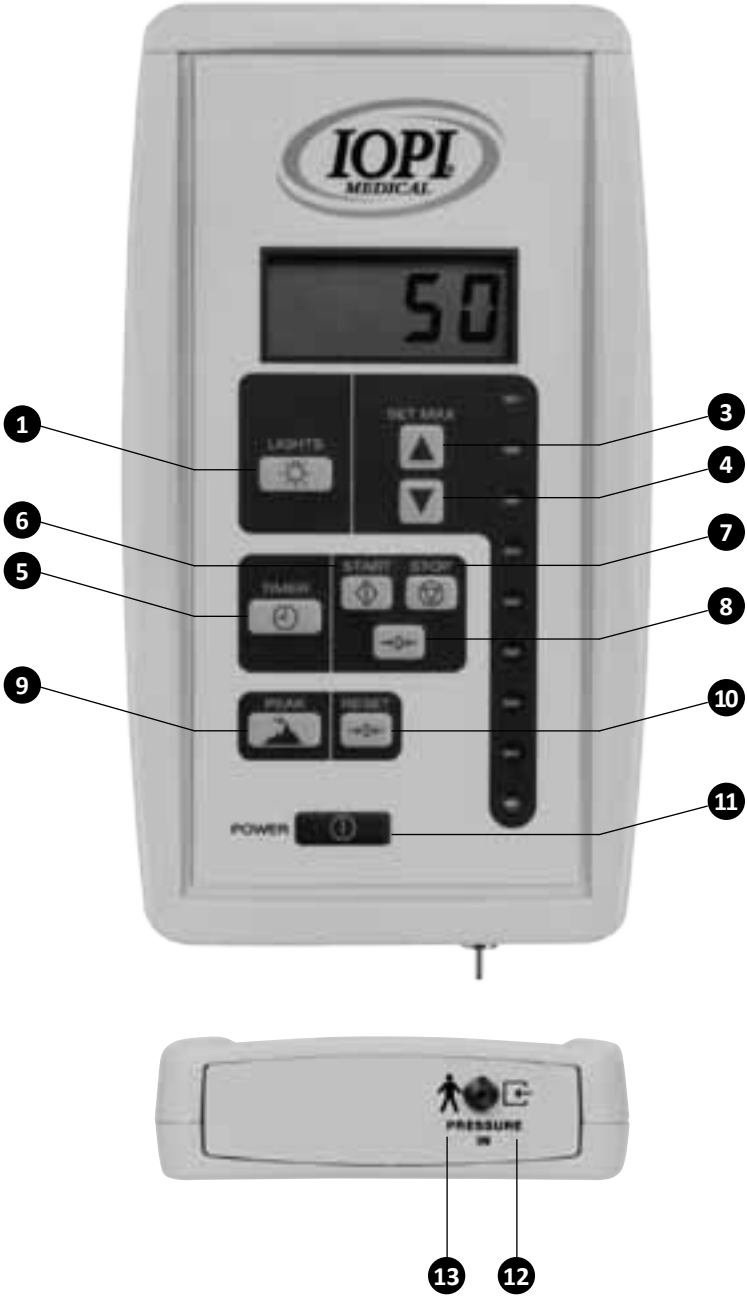
IOPI® Medical LLC approved accessories:

5-6010 Box of Tongue Bulbs
5-0001 Connecting Tube
5-0101 Accuracy Check Syringe

NOTE: Only use IOPI® Medical LLC approved accessories with The IOPI System.

IOPI® Control Buttons

#	Symbol	Identity	Description
1		**Lights Mode**	Toggles the column of lights On and Off. The LCD display shows the target pressure required to illuminate the top (green) light of the light array. When entering Lights Mode, the LCD displays the default target pressure of fifty (50) and one light will be illuminated.
2	SET MAX	**Set Maximum Pressure**	Identifies the buttons for adjusting the target pressure that corresponds to the top (green) light of the light array in Lights Mode.
3		**Adjust Maximum Up**	Increases the target pressure corresponding to the top (green) light of the light array in Lights Mode.
4		**Adjust Maximum Down**	Decreases the target pressure corresponding to the top (green) light of the light array in Lights Mode.
5		**Timer Mode**	When pressed, the LCD display shows the elapsed time, in seconds, between pressing the Start Timer [◇] and Stop Timer [▽] buttons.
6		**Start Timer**	This button will start the Timer.
7		**Stop Timer**	This button will stop the Timer.
8	→0←	**Timer Reset**	This button will reset the Timer to zero (0).
9		**Peak Mode**	Activates a peak-finding function. Displays the maximum pressure achieved when an attached bulb is compressed.
10	→0←	**Peak Reset**	This button will reset the peak-finding function to zero (0).
11		**Power**	Toggles the battery power between On and Off. The IOPI will turn itself off after 15 minutes without a button push or pressure response.
12		**Pressure In**	Short stainless steel tube that connects to female end of Connecting Tube.
13		**Type B**	Patient Isolation: Type B patient applied part according to IEC 60601-1.


IOPI
MEDICAL
50
LIGHTS
SET MAX
TIMER
START
STOP
PEAK
RESET
POWER
PRESSURE
IN
1
3
4
6
7
5
8
9
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11
13
12

Safety & Care Instructions

Safety precautions

Please observe the following safety precautions when setting up and using your IOPI:

- This device is only intended for measuring oral motor structures.
- This device is sold only to medical professionals assisting patients with oral motor problems, including dysphagia and dysarthria. The medical professional is in charge of supervising a patient's use of the IOPI in order to ensure that it is only used as intended.
- To avoid measurement errors, carefully read this manual before using the IOPI.
- Prior to using IOPI accessories (such as the IOPI Tongue Bulb) with the IOPI device, carefully read the Directions for Use for the accessory.

Caring for your IOPI

To ensure that you receive the maximum benefit from using this device, please abide by the following care guidelines:

- When not in use, store the IOPI device in the carrying case provided with the device.
- Do not immerse the IOPI device in water. If the surface of the device comes into contact with water, dry it immediately with a soft cloth.
- To clean the exterior of the IOPI device, wipe it with a soft slightly moistened cloth. Use of mild soaps or disinfectants is suitable. Do not use abrasive or corrosive cleaning agents, as these may damage the unit.
- Remove the 9V battery whenever you plan to store the IOPI device for a long period of time.
- When replacing the battery, only use a new 9V alkaline battery. Do not use a rechargeable battery.
- Do not expose the IOPI device to strong electromagnetic fields, excessive force, shock, dust, temperature changes, or humidity. These environmental conditions may result in malfunction, a shorter electronic life span, or damage to the device.
- Do not open up the IOPI and tamper with the internal components; doing so will terminate the product warranty and may cause damage.
- At the end of its useful life, dispose of the IOPI device and its accessories in accordance with local or national disposal or recycling laws.

How Does the IOPI Work?

How does the IOPI measure strength?

The IOPI measures the Peak pressure a patient can produce in an IOPI Tongue Bulb by pressing the bulb against the roof of the mouth with the tongue. Peak pressure is a measure of strength, expressed in units of pressure, the kiloPascal (kPa).

How does the IOPI measure endurance?

For patients with dysphagia or dysarthria, oral motor fatigability may be of interest. The IOPI can be used to assess tongue fatigability by measuring its endurance, which is inversely proportional to fatigability. Low endurance values are an indicator of a high fatigability.

Endurance is measured with the IOPI by quantifying the length of time that a patient can maintain 50% of his or her Peak pressure. This procedure is conducted by setting the maximum pressure in the Lights Mode to 50% of the patient's Peak pressure and timing how long the patient can hold the top (green) light on.

How is the IOPI used for exercise therapy?

In Lights Mode, the pressure required to illuminate the green light at the top of the light array can be adjusted using the Set Max arrow buttons. This green light is used as a target for the patient. The medical professional determines what target value is appropriate for exercise therapy purposes and provides specific instructions to the patient for a particular exercise protocol. A protocol should include the number of times to illuminate the green light and, for each repetition, how long the green light should be illuminated before releasing pressure on the bulb.

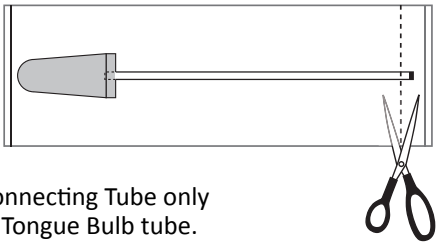
Please visit our website (***www.IOPImedical.com***) for a list of articles providing information about exercise therapy for oral motor structures.

$$T = P_{max} \times \left(\frac{E}{100}\right)$$

T= Target value, P_{max} = Peak tongue pressure, ***E*** = Effort (%)

Set Up

1. Remove the IOPI device from the carrying case and place on a flat surface.
2. Remove the Connecting Tube from the package and notice that it has two ends: a female end (plastic tubing) and a male end (metal).
3. Connect the female end (plastic tubing) to the Pressure Port [⇦] on the IOPI® device by sliding the tubing over the metal port as far as it will go.
4. Look at the Tongue Bulb and notice that one end is a blue bulb and the other end is tubing.
5. Use scissors to cut the seal off the end of the tubing by cutting across the package while the Tongue Bulb is still in its package. *(See image to the right).*



6. Insert the metal (male) end of the Connecting Tube only 2–3 mm into the opened end of the Tongue Bulb tube.
7. Remove the Tongue Bulb from its package to use it with a patient, taking care not to touch the parts of the Tongue Bulb that go into the patient's mouth.
8. Turn the IOPI device on by pressing the Power button [⏻]. The display will show 0 (+/- 1 kPa).

Tongue

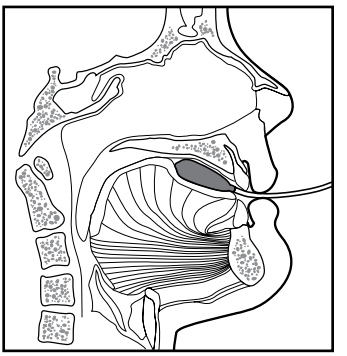
Measuring Tongue Strength

1. With the IOPI® turned on, push the Peak Mode button [⛰]. In this mode, the LCD displays the highest pressure applied to the IOPI.

NOTE: When the IOPI is first turned on, the LCD display shows pressure in a continuous mode.

2. Press the Peak Reset button [→0←]. The LCD display will read "0".
3. Position the Tongue Bulb against the patient's hard palate *(see image to the below).*

WARNING: Hold onto the stem of the Tongue Bulb.



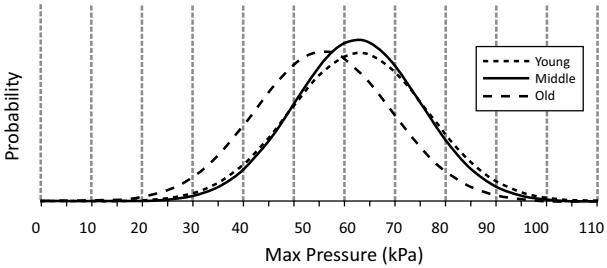
4. Tell the patient: **"Press the Tongue Bulb with your tongue as hard as you can for about 2 seconds**."
   - *Visual and verbal encouragement during the test is acceptable, and helps some people.*
   - *The 2 second hold time is not important; it just avoids the question "How long should I hold it?" when you tell them to squeeze the bulb.*

5. After the patient has made his or her maximum response and relaxed, record the value you see on the IOPI LCD display, and then push the Peak Reset button [→0←].
6. Let the patient rest for 30–60 seconds, and then repeat Steps 3–5 two more times.
7. The Peak tongue strength is the highest of the three recorded values. If the values consistently decrease over the three trials, the rest period may not be long enough.

Tongue Strength Normal Values

These normal values are derived from 10 studies conducted on the US population. New research indicates there may be national variation in these normal values, perhaps dependent on the language spoken by the subjects/patients. For the latest studies that IOPI Medical is aware of, please visit our website.

Estimated normal probability distributions of maximum tongue pressure of three age groups of normal U.S. subjects are shown to the right:



These data were derived from the weighted average of the means and standard deviations of tongue strength of normal subjects reported in 10 publications. Consult "Normal Values" in ***www.IOPImedical.com*** for references and details of the numerical procedures.

Group	Mean	SD	Age (years)	Number of Subjects
Young	63	13.6	20–39	276
Middle	63	12.5	40–60	219
Old	56	13.5	>60	198

Most groups contained approximately equal numbers of males and females. In some studies, males were somewhat stronger than females, by about 5-10 kPa, but only for young subjects. For middle-aged and old subjects, there was no consistent gender difference.

Peak tongue strength values corresponding to various percentiles from the estimated normal distributions are shown below. It is common to consider values below the 5th percentile to be "abnormal" (shaded table cells).

Group	Tongue Strength (kPa)					
	1%	5%	10%	20%	25%	50%
Young	**31**	**41**	**46**	**52**	**54**	**63**
Middle	**34**	**43**	**47**	**53**	**55**	**63**
Old	**25**	**34**	**39**	**44**	**48**	**56**

Measuring Tongue Endurance

1. Measure and record the patient's Peak pressure as described on page 11.
2. Press the Lights Mode button [☼] and note that the bottom light of the light array will turn on and the LCD will display the value 50 (kPa).
3. Use the SET MAX arrows [▲▼] to adjust the value in the LCD display to 50% of the patient's Peak pressure.

NOTE: The top (green) light of the light array will now illuminate when the patient compresses the Tongue Bulb to 50% of their Peak pressure.

4. Place the IOPI so that the light array can be seen easily by the patient.
5. Prepare to use the Timer Mode on the IOPI to measure the length of time that the patient can illuminate the top (green) light.

NOTE: A stopwatch may be used in place of the IOPI's timer feature.

6. To use the Timer Mode, press the Timer Mode button [◴] and notice that the LCD display will show "0" seconds. If the display does not show "0", press the Timer Reset button [→0←].
7. Position the Tongue Bulb in the patient's mouth as described for tongue strength measurement.
8. Instruct the patient to "Squeeze the Tongue Bulb until the top (green) light comes on, and keep it on for as long as possible."
9. When the top (green) light comes on, press the Start Timer button [◇].
10. If if a red light turns on for more than a second, remind the patient to squeeze hard enough to keep the green light on. It is acceptable to encourage the patient "to keep going as long as possible".
11. If the patient cannot illuminate the green light within about 2 seconds, press the Stop Timer button [▽] and tell the patient to relax.
12. Record the time shown in the LCD display.

NOTE: Usually this test is done only once per session with each patient.

Tongue Endurance Normal Values

The data is as yet insufficient to assume the statistical normality of the endurance distributions in the normal population, so an estimate of a normal probability function is not yet warranted. However, the U.S. studies published so far suggest an average endurance of about 30–35 seconds for the tongue. Endurance times of 10 seconds or less would be an indication that a patient probably has low endurance; it may be useful to consider that fatigability is a contributing factor to this patient's oral motor problems.

Lip

Measuring Lip Strength

NOTE: In the following method of measuring lip strength, the bulb is not placed directly between the lips. The described method is valid, however, because the pressure developed in the bulb depends upon the strength of the circumferential muscle complex that surrounds the mouth. It is tension in these muscles that allows the lips to be compressed against one another.

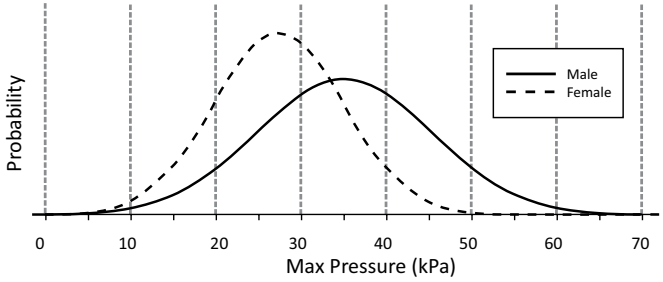
1. With the IOPI on, push the Peak Mode button [ ]. In this mode, the LCD will display the highest pressure applied to the IOPI.
2. Press the Peak Reset button [→0←]. The LCD display will read "0".
3. Position an IOPI Tongue Bulb inside the patient's cheek just lateral to the corner of the mouth.

WARNING: Hold onto the stem of the Tongue Bulb.

4. Tell the patient: "Press the Tongue Bulb against your teeth by pursing your lips as hard as you can for about 2 seconds."
   - *Visual and verbal encouragement during the test is acceptable, and helps some people.*
   - *The 2 second hold time is not important; it just avoids the question "How long should I hold it?" when you tell them to squeeze the bulb.*
5. After the patient has made his or her maximum response and relaxed, record the value you see on the IOPI LCD display, and then push the Peak Reset button [→0←].
6. Let the patient rest for 30 – 60 seconds, and then repeat Steps 3 – 5 two more times.
7. The Peak lip strength is the highest of the three recorded values. If the values consistently decrease over the three trials, the rest period may not be long enough.

Lip Strength Normal Values

An estimated normal probability distribution of a group of 171 normal U.S. persons, aged 18–89, is shown below. Although there were no consistent age differences there was a pronounced gender difference.



Gender	Mean	SD	Number of Subjects
Male	35	10.3	88
Female	28	7.7	83

Data are taken from Clark et al., 2012. No significant differences were found when comparing the right and left lip strengths, so these data have been pooled. See ***www.IOPImedical.com*** for the complete reference of this study, and details of numerical procedures.

References

Please refer to ***www.IOPImedical.com*** for a list of up-to-date references that may be useful for understanding normal values, applications of the IOPI, and protocols that have been published by researchers.

IOPI® Maintenance

Replacing the Battery

1. Replace the battery if the display shows a low battery icon [LO BAT], the display is dim, or if the display does not illuminate when the Power button has been pressed.
2. To replace the battery, slide the battery cover on the back of the IOPI to its fully open position.
3. Install a new 9V alkaline non-rechargeable block battery and connect it to the battery connector, being sure to correctly match the polarity.
4. Slide the battery cover to its fully closed position.

NOTE: Contact your local waste disposal authority for instructions on how to dispose of used alkaline batteries. In Europe, used batteries should be recycled in accordance with council directive 2006/66/EC as transposed into national laws. Do not dispose of in clinic trash.

Accuracy Check

Perform the following accuracy check monthly. Note that this procedure is a check only. If you would like IOPI Medical or an authorized electronics shop to check the calibration rigorously, contact IOPI Medical or your local distributor for instructions.

NOTE: Practice this process a few times until the timing is smooth before you record your readings. The exact starting and ending positions are important.

1. Connect the Connecting Tube to the Pressure Port on the IOPI.
2. Turn on the IOPI and press the Peak button.
3. Set the front edge of the plunger of the syringe just touching the back edge of the 30 ml mark *(see Figure 1)*.
4. Leave the plunger in this position and connect the syringe tubing to the metal end of the Connecting Tube.
5. Over a period of about 5 seconds, depress the plunger so that its front edge ends up just touching the back edge of the 15 ml mark *(see Figure 2)*.
6. Note the peak pressure reading on the IOPI.
7. Disconnect the syringe tubing from the Connecting Tube and push the Reset button on the Peak function.
8. ***Repeat Steps 3–7 several times***. Discard readings if you know you pushed the plunger past the ideal position, or if the depression time was too slow or too fast. If there is variability in the readings, this is due to variability in your method. Repeat until your reading stabilizes (±1 kPa).
9. Using the altitude at your location, compare this pressure reading to Figure 3 (for altitude in meters) or Figure 4 (for altitude in feet).
10. If the pressure reading does not fall within the shaded region of Figure 3 or 4, contact IOPI Medical or your local distributor.

Figure 1.

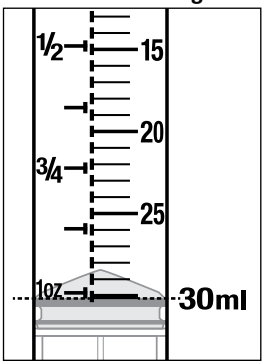


Figure 2.

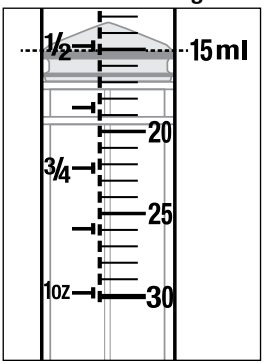


Figure 3.

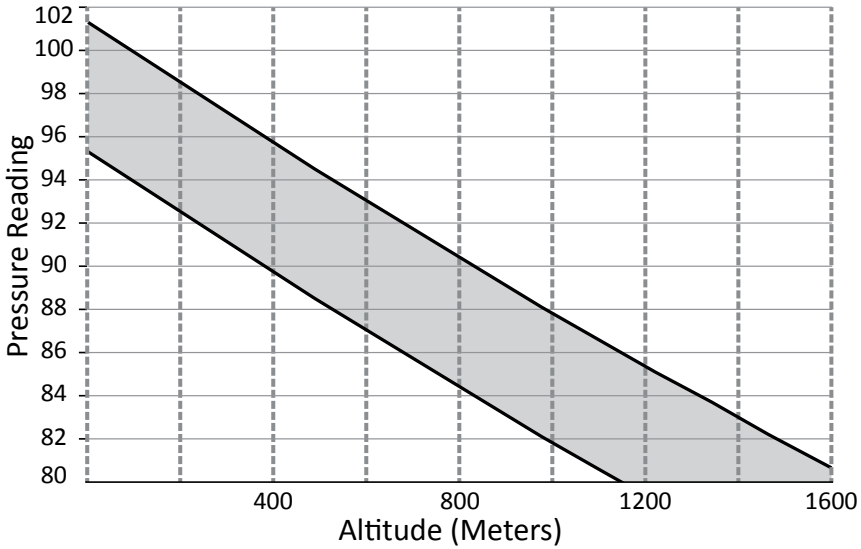
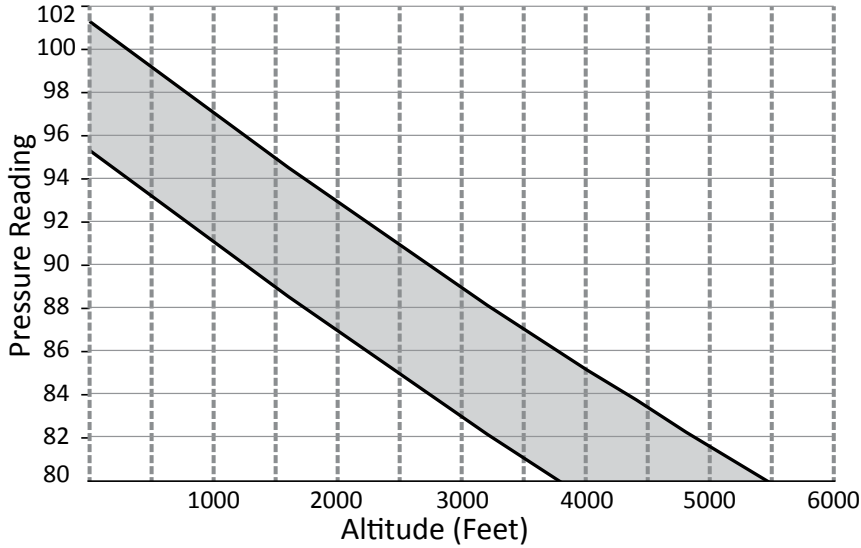
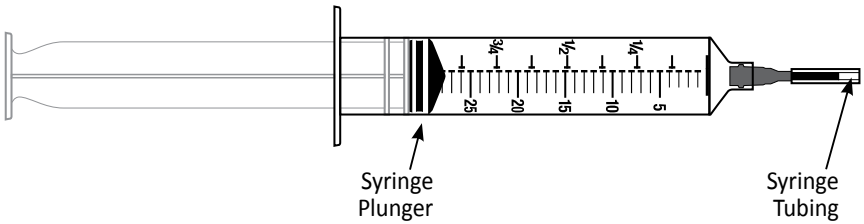


Figure 4.





Troubleshooting

Symptom	Possible Cause	Actions
Tongue Bulb stays flattened or dimpled after compression	An air leak can occur anywhere in the system (Tongue Bulb, Connecting Tube, or inside in the IOPI device itself.)	*1. Determine if the Tongue bulb leaks by trying another Tongue Bulb.* *2. Determine if there is a leak where the Connecting Tube connects to the Pressure Port. Put some soap bubbles around the seam between the Pressure Port and the end of the attached Connecting Tube. Apply a squeeze to a Tongue Bulb and look for soap bubbles that get larger or move around.* *3. While leaks inside the IOPI device are unlikely, if steps 1 and 2 have been tried and the cause of the leak has not been detected, then please contact IOPI Medical LLC or your local distributor as soon as possible.*
Abnormally short endurance values.	A small air leak	*See steps above to determine the source of the air leak.*
The LCD display reads >2 kPa when there is no bulb attached to the IOPI device.	A change in accuracy	*Contact IOPI Medical LLC or your local distributor as soon as possible.*
Peak pressure measurements that seem too high or too low based on experience with the IOPI device and the patient.	A change of accuracy	*Perform an Accuracy Check (see page 16). If the pressure reading is not within specifications, contact IOPI Medical LLC or your local distributor as soon as possible.*
The IOPI device will not turn on.	Battery is dead	*Follow the Replace Battery procedure in the Maintenance section as described on page 15. If the device still does not turn on, contact IOPI Medical LLC or your local distributor as soon as possible.*

Technical Specifications

APPLICATION				
Measuring method	Pressure in an air-filled bulb (in kPa).			
Indications for use	Tongue and lip strength and endurance measurement in patients with oral motor problems, including dysphagia and dysarthria.			
APPLIED STANDARDS				
EN 60601-1, 2nd Ed.				
EN 60601-1-2:2007				
EN 60601-1-6:2007				
ISO 14971:2012				
DIMENSIONS OF IOPI DEVICE				
Height x Width x Depth	18 cm x 10 cm x 2.5 cm			
Weight	258 g			
MEASURING RANGE				
Pressure	0 to 100 kPa			
ACCURACY				
Pressure	±2 kPa			
POWER				
Power supply	9V alkaline battery			
CLASSIFICATIONS				
Protection against electric shock	According to IEC 60601-1; Type B			
Protection against ingress of water	None			
Mode of operation	Continuous duty			
Device Classification	**FDA/US**	**HC/Canada**	**EC - MDD**	**TGA/Australia**
	I	II	I	I
OPERATING ENVIRONMENT				
Temperature	16°C to 27°C (60°F to 80°F)			
Humidity	10% to 83% relative humidity			
STORAGE/TRANSPORT ENVIRONMENT				
Temperature	-20°C to 49°C (-4°F to 120°F)			
Humidity	10% to 83% relative humidity			
MANUFACTURER				
	IOPI® Medical LLC 11920 198th Ave NE Redmond, WA 98053 U.S.A. Tel: +1 (425) 549-0139 FAX: +1 (425) 558-4596			
EU AUTHORIZED REPRESENTATIVE				
EC REP	**EMERGO EUROPE** Molenstraat 15, 2513 BH, The Hague, The Netherlands			
AUSTRALIAN SPONSOR				
	EMERGO AUSTRALIA Level 20 Tower II, Darling Park, 201 Sussex Street Sydney, NSW 2000 Australia			

Limited Warranty

WARRANTY

IOPI Medical LLC warrants your product to be free from defects in material and workmanship for a period of two years from the original date of purchase. If you discover a defect in a product covered by this warranty, we will repair it using new or refurbished components, or if repair is not possible, replace the item.

EXCLUSIONS

This warranty covers defects in manufacturing discovered while using the product as recommended by the manufacturer. The warranty does not cover loss or theft, nor does coverage extend to damage caused by misuse, abuse, unauthorized modification, improper storage conditions, and other failures to use or maintain in accord with the manufacturer's instructions. The warranty does not cover parts that are subject to normal wear and tear.

LIMITS OF LIABILITY

Should the product(s) fail, your sole recourse shall be repair or replacement, as described in the preceding paragraphs. IOPI Medical LLC will not be held liable to you or any other party for any damages that result from the failure of this product. Damages excluded include, but are not limited to, the following: lost profits, lost savings, loss of or injury to data, damage to person or property, and incidental or consequential damages arising from the use, or inability to use, this product. In no event will IOPI Medical LLC be liable for more than the amount of your purchase price, not to exceed the current list price of the product, and excluding tax, shipping, and handling charges.

IOPI Medical LLC disclaims any and all other warranties, express or implied. By using the product, the user accepts all terms described herein.

HOW TO OBTAIN SERVICE UNDER THIS WARRANTY

Before sending the unit for repair, contact IOPI Medical LLC:

+1 (425) 549-0139
sales@iopimedical.com

REQUIREMENTS

The cost of shipping to the manufacturer and payment of any customs clearance fees or duties are the responsibility of the user. These costs may be credited to the user's account if the product is determined to be under warranty. Return shipping costs for products repaired or replaced under this warranty will be paid for by IOPI Medical LLC.

Notes:

Notes:

CE

IOPI MEDICAL

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